

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES**

Application No. **09/834,307**
Inventor: Richard J. Whitbourne *et al.*
Confirmation No. 3036
Filing Date: April 12, 2001
Title TARGETED THERAPEUTIC AGENT RELEASE DEVICES AND
METHODS OF MAKING AND USING THE SAME
Examiner Micah Paul YOUNG
Art Unit 1618
Attorney Docket No. 32286-192724
Customer No. 26694

REPLY BRIEF

Mail Stop: ***Appeal Brief - Patents***
Commissioner for Patents
P.O. Box 1450
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Dear Sir:

In response to the Examiner's Answer mailed December 9, 2009, Appellant timely submits herewith a Reply Brief in accordance with 37 C.F.R. § 41.41. The Notice of Appeal was filed on September 29, 2008, in accordance with 37 C.F.R. § 41.31(a)(3); the Appeal Brief was timely filed on May 4, 2009, in accordance with 37 C.F.R. § 41.37, and corrected on June 26, 2009. A Request for Oral Hearing under 37 C.F.R. § 41.47(b) is being submitted herewith as well as the required small entity fee of \$540 pursuant to 37 C.F.R. § 41.20(b)(3). No other fees are believed to be due for this Reply Brief; however, should any such fee be due, authorization is hereby given to charge any additional fees necessary, and to credit any overpayments, to our deposit account no. 22-0261, referencing our docket no. 32286-192724.

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¹ The Table of Contents is included for reference purposes only and not to limit the issues to be reviewed on appeal.

I. STATUS OF CLAIMS – 37 C.F.R. § 41.37(c)(1)(iii)

The status of the claims remains unchanged from the Appeal Brief. Pending claims 23-67 and 69-83 have been finally rejected. Claims 1-22 and 68 remain canceled.

II. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL – 37 C.F.R. § 41.37(c)(1)(vi)

These Grounds of Rejection to be Reviewed on Appeal are the same as those set forth in the Appeal Brief filed May 4, 2009 (corrected June 26, 2009) and remain unchanged.

A. Whether claims 23-52, 56-59, 61-65, 67, 69-71, 74, 76-78, and 80-83 are unpatentable under 35 U.S.C. § 103(a) as being obvious in view the proposed combination of U.S. Patent No. 5,980,550 to Eder *et al.* and U.S. Patent No. 6,110,483 to Whitbourne *et al.*

B. Whether claims 50, 53-55, 60, 61, 66, 72-75, 77 and 79 are unpatentable under 35 U.S.C. § 103(a) as being obvious in view the proposed combination of Eder and Whitbourne, further in view of U.S. Patent No. 6,335,029 to Kamath *et al.* and U.S. Patent No. 5,589,120 to Khan *et al.*

III. ARGUMENT – 37 C.F.R. § 41.37(c)(1)(vii)

A. No New Grounds of Rejection Were Presented in the Examiner’s Answer

The Examiner’s Answer dated December 9, 2009, does not appear to contain a rejection designated as a new ground of rejection nor does it appear to contain any undesignated new grounds of rejection. *See* M.P.E.P. §§ 1207.03(III)-(IV). Section (9) of the Examiner’s Answer (pages 2-8, ¶¶ 1-14), titled “Grounds of Rejection,” is believed to recite, almost *verbatim*, the same grounds of rejection presented in the Final Office Action (pages 2-6, ¶¶ 1-13) dated May 28, 2008, except for several additional arguments presented in ¶¶ 5-7 of the Examiner’s Answer. These additional arguments are understood to support the previous grounds of rejection and are not believed to constitute new grounds of rejection. Accordingly, the Appellant is not required to exercise the options set forth in 37 C.F.R. §§ 41.39(b)(1)-(2) to avoid *sua sponte* dismissal of the appeal as to claims subject to a new ground of rejection. Nonetheless, the Appellant requests that the appeal be maintained by the filing of this Reply Brief, which is timely submitted in accordance with 37 C.F.R. § 41.41. No new amendment, affidavits, or other evidence are submitted with this Reply Brief.

B. The Office’s “Response to Argument” Does Not Overcome Appellant’s Case on Appeal

In Section (10) of the Examiner’s Answer (*see* pages 8-15), the Office presents its “Response to Argument.” The Examiner’s Answer acknowledges four (4) arguments presented by the Appellant in the Appeal Brief and attempts to address each in order. Specifically, the subsection labeled “1) and 3)” on pages 8-11 of the Examiner’s Answer attempts to address Appellant’s position that one of ordinary skill in the art would not reasonably interpret the coating on Eder’s vaso-occlusive device (in particular, as shown in the illustrative cartoon of FIG. 2) as “bridging from one edge or surface to another across the opening,” as recited in each of the pending claims. The subsection labeled “2)” on pages 11-12 attempts to address Appellant’s position that Ms. Chamberlain’s declaration constitutes evidence and that such evidence was not given due weight in the nonobviousness analysis. Finally, the subsection labeled “4)” on pages 12-15 of the Examiner’s Answer attempts to address Appellant’s position that the combination of Eder and Whitbourne ‘483 do not teach or suggest the recited loadings of the therapeutic agent. Appellant respectfully disagrees with the arguments presented in the Response for at least the following three reasons.

1. The Office Fails to Establish a *Prima Facie* Case of Obviousness Because of Clear Error in its Position on the Scope and Content of the Prior Art

First, with regard to the responding arguments provided in subsection “**1) and 3)**” the Appellant maintains that the Office fails to establish a *prima facie* case of obviousness. “Under § 103, ***the scope and content of the prior art are to be determined***; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined.” *Graham v. John Deere*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966) (emphasis added). Here, the rejections under 35 U.S.C. § 103(a) fail to satisfy even the first step necessary for establishing a *prima facie* case of obviousness – determining the scope and content of the prior art. That is, the Office misconstrues the scope and content of the primary prior art reference (Eder) such that any obviousness rejection based on Eder fails under the *Graham* framework.

Eder relates to a vaso-occlusive device having a bioactive inner coating and a water-soluble outer coating. Eder, Abstract. In particular, FIG. 2 purportedly shows an illustrative view of “a coil having a permanently bonded inner coating and a water-soluble, dissolvable outer coating.” Eder, col. 4, ll. 13-14. Furthermore, “[p]referably, the inner and outer coatings ***do not affect the shape*** of said vaso-occlusive member after deployment.” Eder, col. 3, ll. 44-46 (emphasis added). Thus, Eder’s coating(s) are limited to surface layers formed on, for example, an elongated helical coil and do not show, teach, or suggest any “bridging.” Bridging would affect the shape of a device after deployment.

Although drawings and pictures can be used as prior art where they clearly show the claimed structure, it is also well established that the teachings of all relevant references must be evaluated and applied “on the basis of what they ***reasonably*** disclose and suggest to one skilled in the art.” *In re Aslanian*, 590 F.2d 911, 914, 200 USPQ (BNA) 500 (CCPA 1979) (quoting *In re Baum*, 374 F.2d 1004, 1009, 153 USPQ 190, 195 (CCPA 1967); *see also Ex Parte Deok-Kee Kim et al.*, 2009 WL 505513 at *5 (Bd.Pat.App. & Interf. Feb. 26, 2009)). Eder, including both the written disclosure and the schematic cartoon of FIG. 2, cannot be reasonably read to teach or suggest a “coating bridging from one edge or surface of the substrate to another across the opening” as recited in at least claims 23, 43, 45, 50, and 61.

2. Surface Coatings On A Coil Cannot Be Considered “Bridging”

Second, Eder’s surface coatings on the coil windings and end caps cannot reasonably be said to “bridge” from one edge or surface of the substrate to another across an opening as required by at least claims 23, 43, 45, 50, and 61. The Examiner’s Answer reasons that:

“[B]ridging” as defined by the claims, is a connection between two surfaces across an opening. The claims do not define the orientation of the “bridging” beyond connecting two surfaces. Thus any connection between two surfaces or edges defining an opening would qualify as bridging, meeting the limitations of the claims. The outer coating (part **206**) connects each rise of the coil implant. Further the end caps (parts **104**) are also surfaces that are in relative close proximity defining an opening where the outer coating connecting the parts across the opening defined by the space between the end caps.

Ex. Ans., page 9. The Examiner’s Answer further states that:

It remains the position of the Examiner that any coating connecting two or more surfaces or edges, regardless of how that connection is made would constitute “bridging”. The Specification provides no definition for the term bridging, nor is the shape definitively established. Regardless if [sic] whether the bridging between two surfaces follows the contours of those surfaces or edges or creates its own shape, as long as the surfaces or edges are connected by a coating layer, the claim limitations are met.

Ex. Ans., page 10 (emphasis added). Thus, the Examiner’s Answer apparently takes the position that a surface coating on a coil with end caps constitutes “bridging” according to the claimed invention. The Appellant disagrees and respectfully submits that this position is both unreasonable and unsupported.

The term “bridging” is defined by the intrinsic evidence (i.e., the specification and example embodiments) in the instant application and the Examiner’s position contradicts how one of ordinary skill in the art would understand the term “bridging.” For example, the instant specification explicitly states that:

A “scaffold” is a substrate configured to have adjacent edges or surfaces in close proximity to each other so that *the coating material, when applied, will not only coat the surfaces but will bridge from one surface to the other*. For example, a scaffold may be provided by a wire configured into a coil having open windings. *When the polymer coating is applied to the scaffold,*

it not only covers the surface of the wire but also bridges from one winding to the next so that the finished device may have the shape of a cylinder with the coiled wire scaffold embedded therein. Other scaffolds include perforated wafers, wire meshes, and the like.

¶ [0033] of the published application US 2002/0018795 (emphasis added). Thus, the specification clearly distinguishes between a coating material covering the surface of a coiled wire on the one hand and a coating material “bridging” from one winding to the next on the other. In other words, the object defining an opening to be spanned cannot itself be the element bridging that opening. Moreover, contrary to the statement in the Examiner’s Answer that “Applicant asserts that the total disclosure of Eder (drawings and disclosure) would not teach bridging; however, Applicant provides not [sic] support for this assertion” (Ex. Ans., page 9), the foregoing is believed to provide clear evidentiary support for Appellant’s position regarding the scope of the term “bridging” and the lack of any teaching or suggestion of such feature in Eder.

3. The Obviousness Determination Of The Recited Therapeutic Loading Amounts Lacks A Rational Underpinning and Relies on an Incorrect Reading of Whitbourne ‘483

Third, the Examiner’s strained and bewildering attempt to utilize the disclosure of the instant application to extrapolate the claimed loading values from “by weight” (w/w) percentages of an “active agent” provided in Whitbourne ‘483 is both unreasonable and incorrect. In numbered paragraphs 5-7 on pages 4-6 as well as subsection “4)” on pages 12-14 of the Examiner’s Answer, the Examiner outlines the proposed reasoning underlying the obviousness of the therapeutic loading amounts recited in at least claims 23, 24, 69-71, and 80-83. Unfortunately, the Examiner’s purported reasoning lacks a “rational underpinning to support the legal conclusion of obviousness.” *See KSR Int’l v. Teleflex, Inc.*, 550 U.S. 398, 418, 82 USPQ2d 1385, 1396 (2007) quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).

The Examiner’s Answer apparently attempts to “beef up” the previous rejection of claims 23-52, 56-59, 61-65, 67, 69-71, 74, 76-78, and 80-83 based on Eder in view of Whitbourne ‘483 by citing various composition percentage ranges provided in Whitbourne ‘483 and attempting to extrapolate the same based on the teachings of the instant application to purportedly meet the claimed amounts. This not only impermissibly utilizes hindsight

reasoning gleaned only from the instant disclosure, but also involves glaring misstatements and unchecked calculations to reach unsupported conclusions.

For example, the Examiner's Answer makes the following statements regarding Whitbourne '483:

- "The coatings comprise from 0.01-20% of an active agent (col. 7, lin. 40-55). . . . The coating composition has a thickness of about less than 50 microns (col. 7, lin. 15-20). The thickness of this coating would possess a loading amount well within the limits of the claimed invention." Ex. Ans., page 4, ¶ 5.

In response, the Appellant respectfully submits that such conclusory statements based on disparate portions of Whitbourne '483 do not satisfy the requirement to provide articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. That is, a coating with a thickness less than 50 microns and which comprises 0.01-20% of an active agent (which may include, for example, a hydrophilic polymer, a bioactive agent, and a combination – *see, e.g.*, Whitbourne '48, col. 2, ll. 6-9) in no way necessitates, teaches, or suggests that such coating will have the claimed loading amounts.

The Examiner's Answer also adds the following disjointed argument in support of the foregoing conclusion:

- "The Specification indicates that multiple applications of the layer comprising 0.1% paclitaxel results in a loading of 50-60 micrograms/square cm of the medical coating layer when applied to a standard coil multiple times (Example 3). The Whitbourne patent exemplifies coating layer solution with 0.12% active agent (Example 18), that would result through routine experimentation and application of multiple layers as suggested by Whitbourne (col. 9, lin. 50-60), in a loading within the limits of the claims. . . . Since a compound and its [sic] properties cannot be separated, the coating layers of the Whitbourne patent would inherently result in appropriate loading concentration since they have similar loading percentages to the coatings of the instant claims and comprise similar coating compounds." Ex. Ans., page 5, ¶ 6; page 13.

Notwithstanding the aforementioned problem of impermissibly utilizing hindsight reasoning gleaned only from the instant disclosure, the argument contains notable inaccuracies which further demonstrate that the Examiner's reasoning lacks some rational underpinning to

support the legal conclusion of obviousness. For example, in Example 3 of the instant specification, the by weight percentage of paclitaxel in the “E3 – Med Coat” appears to be orders of magnitude higher than the 0.1% as incorrectly stated by the Examiner. The concentration in solution is about 1%, and the concentration after removal of solvents would be greater than 5%. Additionally, the recited drug loading of 50-60 micrograms in Example 3 is a *total* loading amount obtained on a stainless steel coronary stent, and not a *per area* amount on a “standard coil” as proposed by the Examiner. Furthermore, the Examiner’s citation to a coating layer solution with “0.12% active agent” in Example 18 of Whitbourne ‘483 is unsupported and unclear. In sum, given the aforementioned inaccuracies and misstatements, the Office fails to establish a *prima facie* case of obviousness for failure to properly determine the scope and content of Whitbourne ‘483 and because the proposed reasoning lacks some rational underpinning.

Moreover, the Examiner’s conclusion that the “coating layers of the Whitbourne patent would inherently result in appropriate [i.e., the claimed] loading concentration” (Ex. Ans., page 5, ¶ 6; page 13) cannot withstand scrutiny. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *See* M.P.E.P. § 2112(IV) (citing *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993)). Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. *See* M.P.E.P. § 2112(IV) (citing *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)). Furthermore, “[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” *See* M.P.E.P. § 2112(IV) (citing *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)). Here, the Examiner’s flawed technical reasoning does not demonstrate that the claimed loading concentrations necessarily flow from the teachings of Whitbourne ‘483, nor is the alleged inherency a sufficient basis for an obviousness determination. Whitbourne ‘483 simply does not teach, suggest, or otherwise render obvious, the claimed compositions with respect to the loading concentrations. Accordingly, the Appellant respectfully submits that neither Eder nor Whitbourne ‘483, alone or in combination, teaches or suggests the loading amounts recited in at least claims 23, 24, 69-71, and 80-83.

Reversal of the rejection is respectfully requested.

IV. CONCLUSION

In summary, the Appellant respectfully requests reversal of the rejection of claims 23-67 and 69-83 under 35 U.S.C. § 103(a).

Respectfully submitted,

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